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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,180	02/26/2004	Catherine C. Turkel	17679 (BOT)	9912

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STEPHEN DONOVAN
ALLERGAN, INC.
T2-7H
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,180	TURKEL ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Action is responsive to Applicants amendment and remarks filed February 24, 2005. Claims 1, 7 and 9 have been amended. Claims 10-20 have been added.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's amendment and response the rejection of claims 1-5 and 7-9 under 102(a), pages 2-3, paragraph 2 is withdrawn.

Rejection Maintained

4. The rejection under 35 U.S.C. 103(a) as unpatentable over Katsarava et al in view of Aoki et al is maintained for claims 1-9 and newly submitted claims 10-20 the reasons set forth on pages 3-5, paragraph 3 of the previous Office Action.

The rejection was on the grounds that Katsarava et al teach a study of 98 patients that have medication overuse headaches (see Title and the Abstract). Katsarava et al teach that 71% of the patients had migraine headaches, 14% of the patients had tension-type headaches and 15% had chronic headaches (page 1682). Katsarava et al teach that the study was designed so that patient would withdraw from taking "headache medications"(page 1682). Katsarava et al teach that medication withdrawal relapse rate for patients was 38%. Katsarava et al teach that two predictors for relapse found during the study were type of primary headache and type of overused headache medication (page 1683). Katsarava et al teach that the relapse was lower for patients that suffered from migraine headaches than patients that suffered from tension-

type headaches or a combination of migraine and tension-type headaches (see the Abstract).

Katsarava et al do not teach the use of botulinum toxin to treat headaches and headache related symptoms.

Aoki et al teach a method of treating a tension headache by intramuscular or subcutaneous administration of botulinum toxin to the head or neck location of a patient, thereby relieving tension headache pain (columns 9-10). Aoki et al teach that botulinum toxins types A-G can be used in the invention (see the Abstract). Aoki et al teach that dosages of botulinum toxin used in the invention range from about 0.01 units to about 1000 units (column 4). Aoki et al teach that botulinum toxin can be administered to the facial muscles of a patient (column 1, Example 1).

It would be *prima facie* obvious at the time the invention was made to use botulinum toxin to treat patients that have medication overuse disorder because Katsarava et al teach that medication overuse disorder is associated with patients that have migraine and tension-type headaches and medication withdrawal relapse is more likely to occur in patients that have tension-type headaches. Aoki teach that botulinum toxin can be used to treat patient that suffer from tension-type headaches. One would be motivated to administer botulinum toxin to a patient suffering from medication overuse disorder and chronic headaches since botulinum toxin has been shown to treat patients with headaches, especially tension-type headaches. It would be expected barring evidence to the contrary, that the administration of botulinum toxin to a patient suffering from medication overuse disorder would be effective in preventing the patient against medication withdrawal relapse.

Applicant urges that Katsarava et al only disclose overused medication as the only treatment for medication overuse. Katsarava et al do not disclose any kind of pharmaceutical treatment for medication overuse, let alone use of botulinum toxin to treat medication overuse headaches. Applicant urges that Katsarava et al actually teach away from the use of pharmaceuticals to treat medication overuse headaches. Applicant urges that Aoki et al do not teach or disclose the present invention. Applicant urges that Aoki et al do not supply the deficiencies apparent in Katsarava et al. Applicant urges that references that teach away cannot serve to create a case of *prima facie* obviousness.

Applicant's arguments filed February 25, 2005 have been fully considered but they are not persuasive. It should be remembered that It is the Examiner's position that applicant argues the references individually without clearly addressing the combination of teachings. It is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention.

In response to applicant's argument that regarding establishing a *prima facie* case of obviousness, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would be motivated to administer botulinum toxin as taught by Aoki et al to a patient suffering from medication overuse disorder as taught by Katsarava et al because Aoki et al teach that botulinum toxin has been shown to treat chronic headaches, especially tension-type headaches. To address Applicant's comments that Katsarava et al teach away using pharmaceuticals as a treatment for medication overuse, the Examiner disagrees with this assertion. Katsarava et al teach that medication relapse patients have a high relapse rate within the first year of treatment and is based on the types of drugs overused. Katsarava et al teach that this particularly true for patients overusing tripans. Katsarava et al teach that patients suffering from tension-type headaches have

the highest relapse rates and Aoki et al teach that botulinum toxin has been shown to treat tension-type headaches. One of ordinary skill in the art could reasonably concluded that administering botulinum toxin to a patient suffering from medication overuse would be effective in treating medication overuse relapse. Thus, if headaches are lessened, then medication overuse relapse would lessen, particularly in patients overusing triptan medications. Therefore, it would have been obvious at the time the invention was made to combine the prior art references to arrive at the claimed invention. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

Status of Claims

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 6, 2005

L. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600